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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,512	07/18/2006	Kenji Mishima	NANJP0105US	4612

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EXAMINER

THEISEN, MARY LYNN F

ART UNIT	PAPER NUMBER
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1791

MAIL DATE	DELIVERY MODE
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11/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/586,512	Applicant(s) MISHIMA ET AL.	
	Examiner Mary Lynn F. Theisen	Art Unit 1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Castor (2002/0130430).

3. Castor discloses a process of forming particles by dissolving polymer, bioactive (core substance), supercritical fluid and entrainer or modifier and spraying into a low solubility fluid. See paragraphs 0017, 0018, 0033 and 0038. The low solubility fluid (poor solvent) is water, liquid nitrogen or alcohol [0017]. The supercritical fluid is carbon dioxide, ethane or ethylene (Table 1). The entrainer or modifier is an organic solvent [0003]. Temperature and pressure are controlled. See [0036] and [0003]. The particles are spherical [0011].

4. Claims 1,3-5 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 711 586.

5. The reference discloses forming particles by mixing polymer, solvent (an entrainer) and a supercritical fluid and spraying the mixture into a suitable environment. See column 2, lines 7-40). The environment is air, nitrogen, carbon dioxide, helium, argon or xenon (column 14, lines 41-54) all of which are poor solvents. The supercritical fluid is carbon dioxide, ammonia, ethane, ethylene or butane (column 7,

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lines 50-55). Temperature and pressure are controlled (column 11, lines 30-50).

Pigments (column 18, line 30) or catalyst support (column 23, lines 16-30) would act as a core substance.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 2 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 711 586 in view of Young et al (Rapid Expansion from Supercritical to Aqueous Solution to Produce Submicron Suspensions of Water-Insoluble Drugs).

9. EP 0 711 586 is described above. Young et al discloses spraying a mixture of polymer, solvent and supercritical fluid into an aqueous solution. Water is a poor solvent for the mixture. Using the aqueous prevent agglomeration of the particles. It

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would have been obvious to use an aqueous solution as the suitable environment of EP 0 711 586 because it prevents agglomeration of the formed particles.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-4 and 7-9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9, 11-15, 18,20,21,23-25 and 27-30 of copending Application No. 11/791578. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are encompassed by the co-pending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 5 and 6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9, 11-

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15,18,20,21,23-25 and 27-30 of copending Application No. 11/791578 in view of Castor. Controlling the temperature and pressure in the process of the co-pending claims would have been obvious to one of ordinary skill in the art as Castor shows that this is done in the same type of process.

This is a provisional obviousness-type double patenting rejection.

Response to Amendment

13. Applicant's arguments filed September 18, 2009 have been fully considered but they are not persuasive.

14. Applicants submit that there is difference between the “inject” of Castor and the “spray” of the present claims, In that no rapid expansion is disclosed or suggested by Castor. Castor does not call the process rapid expansion but that is what occurs. A supercritical fluid solution is passed from a pressurize environment through a nozzle to depressurize the solution. The depressurization causes rapid expansion. The depressurization is the same as what applicants, Young et al and EP 711586 call rapid expansion.

15. With respect to EP 711586, applicants state that there is no suggestion for the use of a poor solvent in both the steps of mixing and spraying. The claims do not require that a poor solvent be used in both steps. The claims require an entrainer in the mixing step, there is no limitation that it be a poor solvent

16. Applicants assert that since Young et al is different in purpose from EP 711586 one skilled in the art would not be motivated to combine them. While the references use different methods, they are both directed to rapid expansion to form particles. Both

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expand into a poor solvent, air in one case and water in the other. Young et al shows the advantage of using water.

Conclusion

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Lynn F. Theisen whose telephone number is 571-272-1210. The examiner can normally be reached on Thursday and Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yogendra Gupta can be reached on 571-272-1316. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary Lynn F. Theisen/
Primary Examiner, Art Unit 1791